

SUPPLEMENT

# Designing safer health care through responsive regulation

Judith Healy and John Braithwaite

The health sector is characterised by complexity, a plurality of players (national and state governments, public and private providers, professions, and consumer groups), rapid change in its environment (eg, new technology and new global diseases), and a recent proliferation of regulatory agencies and regulatory strategies. We argue that "responsive" regulation — the use by regulators of mechanisms that are responsive to the context, conduct and culture of those being regulated — is a promising strategy for improving the quality and safety of patient care. These ideas were elaborated in our discussion paper *The governance of health safety and quality*, which presents contemporary research on regulatory thinking, including examples from other high-risk industries.<sup>1</sup> While definitions of regulation abound, we use the term to mean governance in the broad sense of steering the flow of events, rather than the narrow sense of enforced compliance with rules.<sup>2</sup>

In the "new regulatory state", with its increasing privatisation, regulation by government and its agents has become more rather than less common, but the crucial difference from the old "command and control" view is that governments increasingly "steer not row" and are seeking flexible, participatory and devolved forms of regulation. These changes are possible given the changed nature of organisations in the information age, where power flows through networks that are more fluid and complex than older structures of governance.<sup>3</sup> This perspective is particularly appropriate in the health sector with its multiple players and where the state generally has left the regulation of health care performance to the medical profession. However, external pressures have been mounting over the past decade for governance systems to insist on more accountability and transparency from health care providers.<sup>4</sup> Until recently, most mechanisms intended to improve performance have relied on internal rather than external monitoring; for example, hospitals were left to monitor their own surgical mortality rates. The normative assumption has been that techniques for improving performance rely on voluntary adoption by a professional or an organisation, whether incident reporting or clinical protocols. Walshe argues that the problem with this "soft" approach is that it treats a health provider as if it exists in isolation from its environment, oblivious to the institutional, social and economic pressures that drive organisational willingness to contemplate internal reforms.<sup>5</sup> Moreover, the medical profession has traditionally resisted what it sees as encroachment on professional autonomy,<sup>6</sup> although, in the United Kingdom at least, it has been claimed that the old system of self-regulation by doctors is dead.<sup>7</sup>

The public expects a high standard from 21st century health care given the dramatic advances in technology and in medical and surgical knowledge. However, greater scrutiny of performance, and more media interest in its failings, has shaken public confidence. Ongoing medical "scandals" in many countries, including Australia<sup>8</sup> — most recently at Bundaberg Hospital<sup>9</sup> — mean that the public is no longer confident about leaving safety and quality to doctors and health departments. Realisation has dawned that health care is a risky business, as shown by the Quality in Australian Health Care Study, where re-analysis of data revealed that over 10% of patients experience some type of adverse event in

## ABSTRACT

- Self-regulation by the health professions, while improving, is no longer enough; external drivers for safer health care include governments, funders and consumers.
- Enforced self-regulation is often more promising than a "command and control" strategy.
- Research evidence on the responsive regulatory pyramid and its options offers lessons for health care policy makers and managers.
- Start at the base of the regulatory pyramid — try persuasion first; move up the pyramid to secure compliance, and then be willing to move back down.
- Use existing capacities and structures, and if possible avoid new bureaucracies of control.

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hospital.<sup>10</sup> Estimates and consensus from other countries suggest that a large proportion of errors are preventable.<sup>11,12</sup>

## What should be done: the case for responsive regulation

The challenge for safety and quality is to design safer systems and inculcate a culture of safety, while the challenge for governance is to ensure that these systems and practices are actually applied. The argument of responsive regulation is that regulators are more likely to succeed if they use strategies that are responsive to the culture of those being regulated.<sup>13</sup> For example, bringing about change in hospitals must take into account professional and organisational cultures,<sup>14</sup> as shown in the research on "magnet" hospitals (so termed because of their success in attracting and retaining nursing staff).<sup>15</sup> Similarly, designing safer systems must take into account human factors.<sup>16</sup>

Responsive regulation is an approach that values trust, transparency and professionalism. It aims to transcend the polarised choice between punishment and persuasion. The regulatory pyramid is an attempt to solve the puzzle of when to persuade and when to punish. Key elements of responsive regulation are:

- The regulator begins at the base of the pyramid with persuasion;
- A single regulatory mechanism is seldom sufficient as the weaknesses of one mechanism must be complemented by the strengths of another; and
- There must be the capacity for escalation if persuasion fails.

At the base of the pyramid, we must craft the most persuasive and dialogue-based approach for securing compliance with a just rule or standard, through invoking informal rewards such as praise, rather than sanctions. The presumption is to start at the base of the pyramid ("soft words before hard"), but, in ascending, to invoke more demanding strategies. The pyramidal presumption of persuasion gives the cheaper and more respectful option a chance to work first. Polite requests followed by threats are more likely to work when everyone knows that non-compliance will result in an inexorable progression up the enforcement pyramid,

**1 Regulatory pyramid and examples of safety and quality mechanisms (from Braithwaite et al, 2005<sup>1</sup>)**

and that “owning up” results in learning, while cover-up risks escalation.

Box 1 depicts some examples of regulatory mechanisms from the health sector that range upwards in a pyramid from persuasion to punishment — although some mechanisms, such as accreditation, might be voluntary or mandatory depending on the context. Thus, a policy maker or hospital manager could use the pyramid to think responsively in choosing among a range of regulatory options.

The idea of responsive regulation is that informal interventions to address problems, as well as positive feedback on achievements and strengths, may be all that is required to persuade a health provider. Persistent infractions may eventually elicit repeat inspections and public disclosure of failure to meet standards. But, even at this level, referral to support services or mentoring should be offered. Every escalation up the pyramid should also indicate a path to de-escalation. Continued and serious breaches of the regulatory guidelines may incur financial penalties and result in activities being curtailed. For example, a hospital might be refused public funding for extra elective surgery until a problem is fixed, or a physician might be deregistered. Licence removal or closure are last resorts and signal the failure of both parties to ensure the public is well served.

The idea of responsive regulation arose out of the actual experiences of private firms. Some argue that business people

understand only the “bottom line” profit and therefore must be consistently punished for lawbreaking, while others assert that business people are responsible citizens who can be persuaded. There is truth in both positions, depending on the context. But neither consistent punishment nor consistent persuasion has proven effective in the long term. Consistent punishment is too costly, and consistent cajoling of the incorrigibly unethical or incompetent is naïve. For example, a study of 410 chief executive officers of small health care organisations found that while expected severity of sanctions did not predict compliance, regulators who were consistently “tolerant and understanding” increased non-compliance.<sup>17</sup> Although there is no body of evidence that responsive regulation will work in more complex organisations such as hospitals — that remains to be tested — there is a body of evidence that responsive regulation works in settings such as mines and nursing homes, and also in more complex domains, such as the nuclear industry.<sup>18</sup>

**Where the gaps are in regulatory options**

Despite the emergence of new regulatory bodies, commentators in several countries, including the United States<sup>19</sup> and Australia,<sup>20</sup> are frustrated by an apparent lack of progress. This is despite the large body of widely disseminated research and recommendations over the past 5 years by the Australian Council for Safety and Quality in Health Care, and the host of initiatives underway.<sup>21</sup> For example, there are no national published measures of adverse events, despite the beginnings of state-based monitoring of sentinel events. Without some form of standardised reporting, there is no way to benchmark performance and to systematically trace progress.<sup>20</sup>

A second gap is in innovation through systematic learning, as undertaken in other risky enterprises. For example, this philosophy underwrote the dramatic improvements in the safety of air travel in the 20th century. The aviation industry has systematised error reporting and staff training to produce a safety culture that offers lessons for medicine.<sup>22</sup> The challenge for health care is to shift from a blame culture to a learning culture, in order to learn from adverse events.

**What we should do: hard and soft regulation**

Two approaches — metaregulation and learning models — illustrate how we might rise to the challenge of shifting from blame to learning.

**Metaregulation (enforced self-regulation)**

In metaregulation, an external regulator checks that a self-regulator is regulating internally to standards that are externally acceptable. It is publicly regulated self-regulation: private rule enforcement, publicly monitored. External regulation may act through a governance network, as it is important that health providers manage not only their own risks, but also the way their network partners manage their risks. For example, a medical “scandal” in one hospital generally has repercussions for others. Everyone learns how to continuously improve by monitoring everyone else, and thus governance is not top-down but collaborative.

A metaregulator needs power to enforce self-regulation when an issue requires both the problem-solving creativity of self-regulation, and the assurance that minimum standards are met. This

concept underlies the framework of clinical governance introduced into the UK National Health Service (NHS) in the late 1990s.<sup>23</sup> The Healthcare Commission, as the metaregulator, now regularly reviews the progress of NHS health providers in implementing quality improvement systems and achieving better outcomes.

Another example of enforced self-regulation is an external requirement that every hospital must implement an infection control plan and plot infection outcomes over time. Innovative hospital administrators are permitted to design their own standards and programs, as long as they make a good case that their standards are better than the default standards.<sup>19</sup> Dynamism can be built into enforced self-regulation to prod reluctant managers by requiring continuous improvement. This means that, each year, managers are required to do something to make infection control better than last year. The tough part about enforced self-regulation is that, unlike voluntary self-regulation, it is enforceable. Hence, if a hospital fails to meet one of the privately written but publicly ratified rules, the organisation and its managers can be sanctioned for that failure. This enforced self-regulation strategy attempts to secure the creativity, flexibility, and cost-effectiveness of moving away from command and control, while simultaneously retaining public enforcement capability.

One of the hopes for well crafted meta-risk management is that it will foster creative approaches to continuous improvement. An example is the nursing home industry in the US, where homes were required to identify their greatest health quality problems, choose one to improve each year, design an intervention, and measure the targeted outcome before and after the intervention. Because the level of restraint of elderly people in nursing homes was such an obvious problem (40% of residents nationally were physically restrained), many nursing homes were pushed to target this issue for their quality improvement study. Between 1990 and 2005, the proportion of residents physically restrained dropped from 40% to 4%.<sup>24</sup> This was accomplished not by a "command and control" rule, but by the industry's own management creativity in finding better ways to manage patients without tying them into a chair or bed.

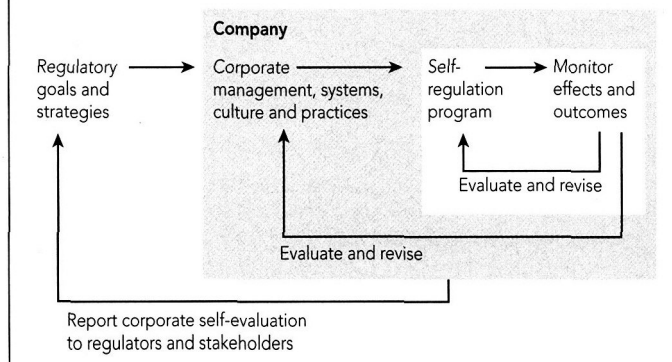
The more complex and dynamic the care process (as in a hospital versus a nursing home), the more relevant a policy of devolution of management decisions closer to the complexities of managing staff and patients. In addition, a regulatory strategy that harnesses management creativity to deliver continuous improvement in quality allows leaders to raise the standards of the whole sector.<sup>25</sup>

### Learning models

Doctors are no longer expected to rely solely on their own clinical judgement or to apply received wisdom from their teachers (handed down perhaps decades ago), but instead to practise evidence-based medicine, or at least to consult guidelines and clinical protocols as to contemporary best practice. Triple-loop learning (Box 2) takes voluntary regulation some steps further.<sup>26</sup>

The first loop occurs when self-regulatory innovators monitor their effectiveness at improving an outcome. An example is a personal learning model using portable digital technology to enable reflective practice.<sup>27,28</sup> The second loop occurs when policy learning is monitored by clinicians and senior managers who, in response, change their management systems, culture and practices. An example is the research collaborations between health

## 2 Triple-loop learning (from Parker, 2002<sup>26</sup>)



providers that support the creativity of professionals in solving their own quality problems.<sup>29</sup> The third loop occurs when a regulator (such as an accreditation agency or a health department) learns from monitoring the organisation's double-loop learning and revises its regulatory goals for the whole field.

The slow translation of evidence into practice by doctors<sup>30</sup> has prompted the establishment of dissemination bodies, such as the National Institute of Clinical Studies, which hope to improve the take-up in clinical practice of the best available evidence — in other words, to promote triple-loop learning. Until now, the movement from single to double to triple loops of learning has not been systematic.

In a hospital, the loops of learning to improve safety are multiplied. Hospital managers might require the staff on each ward to meet annually to identify and discuss their biggest safety problems, and then to design one improvement project for that ward and to measure its outcomes. A reason to do this ward by ward is that different kinds of wards have different kinds of problems. However, sometimes the targeted problem is of general importance, such as infection control. If a ward devises a simple way of improving infection control, hospital managers can spread the success story to all wards of the hospital. An accreditation agency can learn from this and spread the story of this hospital's success across the country. The fourth loop of learning might come when a researcher evaluates and publishes the results of this infection management program in a peer reviewed journal.

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